

Why meta-regulation matters for public health: The case of the EU better regulation agenda

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Abstract:

Meta-regulation – the rules that govern how individual policies are developed and reviewed – has not received much attention in the study of health policy. We argue that these rules, far from value-free and objective, have significant potential to shape policy outputs and, as such, health outcomes. Channelling and operationalising wider paradigms like neoliberalism, they determine, for instance, what is considered 'good' policy, how decisions are made, based on which evidence, and whose voices matter. Exploring an archetypal example of meta-regulation, the European Union's Better Regulation agenda, we illustrate why meta-regulatory tools such as impact assessment, stakeholder consultation, and evaluation – and the norms that underlie their application – matter for health. In so doing, we concentrate especially on the ways in which Better Regulation may affect interest groups' ability to exert influence and, conversely, how actors have sought to shape Better Regulation. We argue that attention to meta-regulation contributes to counter-balancing the focus on agency within debates at the intersection of globalisation and health, and notably those on regulatory practices and coordination. Whilst research has noted, for instance, the origins of frameworks like Better Regulation and the increasing inclusion of 'good regulatory practice' provisions within trade and investment agreements, less attention is directed to the role that these frameworks play once institutionalised. Yet, as we illustrate, there is considerable scope for meta-regulation to enhance our understanding of the forces shaping health policy via, for instance, conceptualisations of the (social, economic, political, commercial) determinants of health. As such, we call for increased attention to the role of meta-regulation in research and practice aimed at improving human and planetary health.

Core messages and definitions:

- Studies have looked at the role of actors, ideas, and politics in shaping public health policy outcomes. Literature has recently explored how these are shaped by structural drivers such as neoliberalism and globalisation, for instance looking at how commercial actors prevent or undermine equitable policies. By contrast, the role of the wider structures within which actors operate has been neglected.
- In that regard, the article introduces the notion of meta-regulation as a structural factor. Meta-regulation can be defined as "the rules that govern the rules". It corresponds to the institutional structures and settings that define interactions and decision-making processes across all policy sectors within a political system. Meta-regulations determine what is considered 'good' policy, how decisions are made, based on which evidence, and whose voices matter. Meta-regulation shapes, and is shaped by, agency. It is therefore a vehicle for political agendas and interest representation and is subject to lobbying.
- Meta-regulation aimed at "bettering" the quality of policymaking processes is now common, especially following efforts from the OECD in promoting "good regulatory practice". However, meta-regulation is rarely considered when analysing the different determinants of health.
- The paper looks at how Better Regulation enables and constrains actors' ability to influence the health policy process, and how actors, in turn, seek to shape the Better Regulation agenda.

Better Regulation: an example of meta-regulation

- Meta-regulation sets the course of decision-making and many of the parameters within which those seeking to shape policy operate (which department leads on a particular file, the range of consultation, how the impacts should be assessed). This explains the motive behind the push by some governments and multinational companies for mandatory impact assessment in the EU, and for the extension of good regulatory practice frameworks through trade agreements.
- Better Regulation is a meta-regulation. Applicable to all policy sectors, it sets out the precise procedures that EU officials must follow when creating or revising policies, the principles and objectives that should inform policy development, and the role of particular actors and tools at different stages of the policy process. The agenda was pushed in the EU by Member States such as the Netherlands and the United Kingdom, along with corporate actors. The EU Better Regulation framework has evolved but the comprehensive version that structures current policymaking was adopted in 2015 and amended in 2019 and 2021.

What is Better Regulation?

- Better Regulation seeks to improve the quality of EU legislation by strengthening its evidence base, increasing participation in policymaking, and reducing the burden of legislation for businesses and citizens.
- The agenda contains five policy tools:
 - Impact assessment
 - Evaluation
 - Consultation
 - Quality control
 - Regulatory stock management.
- In addition to these tools, Better Regulation contains a set of principles to guide decision-making:
 - Proportionality means that EU action should not go beyond what is necessary to achieve the desired outcome.
 - Subsidiarity establishes that EU action should not proceed unless it is more effective than action taken at the national level.
- Several non-Treaty principles have been included as well:
 - ‘Think small first’, focusing on small and medium enterprises
 - Mainstreaming EU action on the Sustainable Development Goals
 - ‘Digital by default’, advancing the EU’s ‘digital transition’ policy
 - Ensuring the European Green Deal pledge to ‘do no significant harm’ to environmental objectives
 - Integrating ‘strategic foresight’ into decision-making
 - The innovation principle, committing the EU to systematically consider impacts on firms’ “capacity and incentives to innovate”.

Better Regulation and lobbying

- Overall, the tools and principles introduced above shape and are shaped by the agency of the different actors taking part in policy-making. In this case, lobbying the Better Regulation agenda is an example of lobbying “one level up”, i.e., beyond the scope and content of a sector specific issue. Industry groups have included Better Regulation and its principles in their advocacy strategies. Recently, civil society organisations included

Better Regulation in their advocacy and launched counter-campaigns which highlight the potential threat that the current agenda poses to health and environmental protections.

- In 2015, a coalition of civil society organisations launched the Better Regulation Watchdog. The group aimed at resisting the weakening and neglect of essential regulations. However, the group's activities decreased, while corporate actors continue to be more successful in shaping the Better Regulation agenda.

Lessons learnt

- The paper explains that:
 - Better Regulation tools can be used instrumentally: requirements for specific evidence as part of impact assessment exercises, for instance, can be the opportunity to informally challenge a policy. For example, in the case of the chemicals regulation (REACH), in the early 2000s, industry groups commissioned several consultancies to produce alternative assessments to the one of the Commission, and managed to have several of these included in the Commission's impact assessment framework. In addition, the requirement to conduct increasingly complex impact assessments risks delaying much needed policy action, especially with additional delays possible following the assessments of the Regulatory Scrutiny Board. Regarding consultation, while it enables a wide range of actors to take part in policy making, it also risks privileging corporate interests that have more resources to take part.
 - Narratives can be formed around the Better Regulation agenda and its principles. The EU's own narratives can be used strategically by those seeking to shape policy. For instance, the emphasis on burden reduction suggests that some regulations should be cut. The industry tends to use Better Regulation in their narratives when trying to block, delay, or weaken regulatory action.
- The paper shows that there is a need to look beyond specific policy areas, focus on meta-regulation, and look at policy actors' ability to shape the latter and use it in their favour. Focusing on it would help understanding what should change upstream to support a policy environment that encourages equitable health outcomes. The way interest groups took part in shaping the Better Regulation agenda shows that there needs to be attention paid to the politics behind the choice of governance tools.